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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,586	04/26/2006	Oliver William Hardwicke Davies	DI5015USNP	3793
7590 07/23/2008				
Johnson & Johnson International Patent Law Division P.O. Box 1222 New Brunswick, NJ 08901			EXAMINER NGHIEM, MICHAEL P	
			ART UNIT 2863	PAPER NUMBER
			MAIL DATE 07/23/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

10/577,586

## Applicant(s)

DAVIES ET AL.

## Examiner

MICHAEL P. NGHIEM

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The Amendment filed on April 22, 2008 has been acknowledged.

#### ***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: claims 1, 3, 7, and 9, "... the interferant current produced at the uncovered area is proportional to interferant current produced overall" is not described in the specification.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 3, 7, and 9, are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the

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steps. See MPEP § 2172.01. The omitted steps are: steps that tie measuring first and second current steps with the calculating a corrected current value. The calculating a corrected current value step is independent from the measuring a first current step and measuring a second current step.

The remaining claims are also rejected under 35 U.S.C. 112, second paragraph, for being dependent upon a rejected base claim.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321 may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3 of copending Application No. 10/977,292 (Davies et al.). Davies et al. claims:  
Regarding claims 1 and 3, a method of reducing interferences in an electrochemical sensor (claim 1, lines 1-2; claim 3, lines 1-2) comprising:

measuring a first current at a first working electrode, said first working electrode having an area being covered by a reagent layer (claim 1, lines 3-5; claim 3, lines 3-5);

measuring a second current at a second working electrode, having a covered area coated by the reagent layer and an uncovered area not coated by the reagent layer (claim 1, lines 6-9; claim 3, lines 6-10)

calculating a corrected current value representative of a glucose concentration using a ratio of said covered area to said uncovered area of said second working electrode (claim 1, lines 10-13; claim 3, lines 12-15) to reduce the effects of interferants (claim 1, line 1; claim 3, line 1).

Regarding claim 2, said corrected current value is calculated using the "claimed" equation,

where G is the corrected current value, WE1 is the uncorrected current density at said first working electrode, WE2 is the uncorrected current density at said second working electrode, A<sub>cov</sub> is the coated area of said second working electrode, and A<sub>nc</sub> is the uncoated area of said second working electrode (claim 2).

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Regarding claim 4, said corrected current value is calculated using the "claimed" equation:

where

$$f1 = A\_cov1/A\_unc1;$$

$$f2 = A\_cov2/A\_unc2;$$

$A\_unc1$  is an uncoated area of said first working electrode;

$A\_unc2$  is an uncoated area of said second working electrode;

$A\_cov1$  is a coated area of said first working electrode;

$A\_cov2$  is a coated area of said second working electrode;

$G$  is the corrected current value;

$WE1$  is the uncorrected current density at said first working electrode; and

$WE2$  is the uncorrected density at said second working electrode (claim 4).

Regarding claim 1, although the conflicting claims are not identical, they are not patentably distinct from each other because even though Davies et al. does not claim interferant current produced at the uncovered area is proportional to interferant current produced overall of the second working electrode, Davies et al. claims a ratio between the covered and uncovered areas of the second working electrode (claim1, lines 10-13; claim 3, lines 12-15). Therefore, a ratio between the uncovered area and the overall area can be determined. In other words, the uncovered area is proportional to the overall area. Thus, one of ordinary skill in the art could determine that the interferant

current produced at the uncovered area is proportional to interferant current produced overall of the second working electrode.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 5 and 6 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3 of copending Application No. 10/977,292 (Davies et al.) as discussed above and further in view of Davies et al. (US 2002/0092612). Even though Davies et al. ('292) does not claim the interferant comprises one or more of acetaminophen, gentisic acid, uric acid, and combinations thereof, this limitation is common knowledge since Davies et al. ('612) discloses that interferant comprises one or more of acetaminophen, gentisic acid, uric acid, and combinations thereof (paragraph 0020, lines 1-3) are oxidized on electrode surface.

This is a provisional obviousness-type double patenting rejection.

Claims 7-10 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 3 of copending Application No. 10/977,292 (Davies et al.) in view of Huang (US 2004/0149578). Regarding claims 7-10, Davies et al. ('292) claims the limitations as discussed above regarding claims 1-4 above. However, regarding claims 7 and 9, even though Davies et al. does not claim a first and second working electrodes disposed on a substrate and an insulation disposed

over electrodes and the substrate, the insulation having an opening to allow a reagent to contact portions of the first and second working electrodes, this limitation would be obvious because Huang discloses a first and second working electrodes disposed on a substrate and an insulation disposed over electrodes and the substrate, the insulation having an opening to allow a reagent to contact portions of the first and second working electrodes (paragraphs 0052; paragraph 0113), for the purpose of providing an insulated electro-mechanical sensor for testing an analyte (paragraph 0113).

This is a provisional obviousness-type double patenting rejection.

#### ***Allowable Subject Matter***

Claims 1-10 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, and double patenting rejections set forth in this Office action.

#### ***Reasons For Allowance***

The **combination** as claimed wherein a method for reducing interferences in an electrochemical sensor comprising calculating a corrected current value representative of a glucose concentration using a ratio of said covered area to said uncovered area of



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said second working electrode (claims 1, 3, 7, 10) is not disclosed, suggested, or made obvious by the prior art of record.

### ***Response to Arguments***

Applicant's arguments filed on April 22, 2008 have been fully considered but they are not persuasive.

Examiner maintains the 35 USC 112, 2<sup>nd</sup> paragraph rejections as discussed above.

Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

### ***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Nghiem whose telephone number is (571) 272-2277. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Barlow can be reached on (571) 272-2269. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael P. Nghiem/

Primary Examiner, GAU 2863

July 16, 2008